UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BIOPURE CORPORATION SECURITIES LITIGATION	Civ. No. 03-12628 -NG

PROPOSED PLAINTIFFS' POST-ARGUMENT SUPPLEMENTAL SUBMISSION IN SUPPORT OF PLAINTIFFS' MOTION TO AMEND COMPLAINT

A lynchpin of Defendants' argument in opposition to Plaintiffs' Motion to Amend Complaint (Docket No. 82) has been that Defendants' failure to publicly disclose the FDA's clinical hold on Hemopure trauma trials, during the Class Period, did not render the Defendants' public statements, during the Class Period, regarding Biopure's Biologic License Application for approval of Hemopure ("BLA"), materially misleading because the FDA's clinical hold on trauma trials for Hemopure was not related to the BLA. As Defendants' counsel stated at the February 2, 2006 hearing on the Motion to Amend (the "Hearing"):

> MR. BUHLMAN: ...[T]he clinical hold...did not make any of [Biopure's] disclosures about the BLA misleading because **the hold had nothing to do with the BLA**.

Hearing Tr. at 14, emphasis added.

At the Hearing, this Court crystalized the issue in response to defense counsel's statement that "[Plaintiffs' counsel] can't mix those two regulatory reviews and pick from the trauma status":

> THE COURT: ...If one can fairly interpret the FDA's communications as doing that mix, in other words, it's not that [Plaintiffs' counsel] is sort of taking this out of context, the question is whether the FDA in its correspondence implied that because of concerns about one, they were stopping the other, and therefore, raised concerns about both.

Hearing Tr. at 56.

Plaintiffs have now learned an additional fact, previously unknown to them, which directly responds to the question posed by this Court.

The Defendants received two significant letters from the FDA on July 30, 2003. As reflected in the Second Consolidated Amended Complaint:

> On July 30, 2003, Biopure received two highly significant letters from the FDA. One was a letter once again refusing to lift the clinical hold on the Trauma Clinical Trials (the "July 30, 2003 Trauma Clinical Trials Letter"). It was received by Defendants Moore and Richman on or about July 30, 2003 and about which Biopure's General Counsel was made aware no later than July 31, 2003. The other was FDA's Complete Response Letter (the "Complete Response Letter")....

Id., ¶98.

We now know, from the Defendants' disclosure in Defendants' Reply Memorandum In Support of Defendants' Motion for Partial Summary Judgment (Docket No. 90 in the SEC Action) (the "Defendants' Reply Memorandum"),[1] that:

> ...**the July 30 trauma letter was *virtually identical* to the July 30 BLA letter in terms of questions asked**. **The first 14 pages of the trauma letter are verbatim questions copied from the first 13 pages of the BLA letter**. Compare SEC Ex. 49, pp. 1 - 14 with SEC Ex. 48, pp. 1 - 13. **The trauma letter made only *two* comments on the last page that did not appear in the July 30 BLA Letter....**

Id. at 6 - 7, italics emphasis in original, bold emphasis added.[2] This demonstrates that the

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[1] The Defendants' Reply Memorandum was filed on February 16, 2006 in *SEC v. Biopure, et. als.* No. 05-11853-PBS (the "SEC Action"), and is attached hereto as Exhibit A.

[2] Plaintiffs understand that SEC Ex. 49 is the July 30, 2003 Complete Response Letter, which is Exhibit B to the SCAC, which Plaintiffs obtained when it was publicly filed by the Defendants in the SEC Action. Plaintiffs understand that SEC Ex. 48 is the July 30, 2003 Trauma Clinical Trials Letter. All of the SEC's filings in the SEC Action, in response to the Defendants' Motion for Partial Summary Judgment, including SEC Ex. 48, have been filed under seal and hence are unavailable

trauma clinical hold was intimately related to, and directly and materially impacted, the BLA and, moreover, that Defendants were fully aware of this direct relationship.

In response to the Court's question quoted on page 1, *supra*, Defendants' counsel said:

> MR. BUHLMAN: ... If FDA, and this to me is a very compelling way to make this point, when they did communicate about the BLA, and we all agree that the July 30 BLA letter is about the BLA, they did not raise the questions about the trauma that he's saying had some implication in April. He isn't entitled to an inference that is flatly contradicted by another part of the record that's been put before the Court, and we have **the July 30 BLA letter**, and **it's not about the trauma hold or the hold questions**.

Hearing Tr. at 56-57, emphasis added.

That argument is utterly vitiated by the fact, disclosed and admitted by the Defendants in their Reply Memorandum, that the two July 30, 2003 FDA letters were "*virtually identical*." (Ex. A at 6).

The identicalness of the July 30, 2003 Complete Response Letter and the Trauma Clinical Trials Letter also belies other arguments made by Defendants' counsel at the February 2, 2006 Hearing, including:

> MR. BUHLMAN: ...[W]hen FDA put the trauma trial on hold, it referred to data in the BLA, but that didn't mean that they were making a conclusion about the BLA which was still a separate indication for surgery patients. ... [I]t didn't represent in any way a communication about the substance of the BLA review which was ongoing.
>
> And, your Honor, I can demonstrate that quite convincingly by reference to the July 30 BLA letter... When you look at the July 30 BLA letter, which was

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to the Plaintiffs at bar. This demonstrates how the Plaintiffs continue to be prejudiced by their lack of access to the documents provided by the Defendants to the SEC in the SEC Action and why the pending Motion to Partially Lift the Automatic Stay of Discovery Provided Under the Private Securities Litigation Reform Act with Respect to Documents that Defendants Have Already Produced to the SEC (Docket No. 80) should be granted.

> the substantive communication about the BLA review, the FDA did not communicate safety concerns based on the trauma questions that they asked.

Hearing Tr. at 19-20.

> MR. BUHLMAN: ...So there's absolutely no factual basis for the plaintiffs to ask this court to infer that the trauma clinical hold delayed or slowed down the BLA review....
>
> So, the fundamental flaw in the plaintiff's persistent reference to this trauma hold impacting the BLA review is that **there's actually absolutely no factual basis, even taking their assertions as true, to draw that link**... .

Hearing Tr. at 21-22, emphasis added.

> MR. BUHLMAN: ...**None of what [Plaintiffs have] pleaded...amounted to knowledge by anyone that the BLA and the trauma hold were in any way interrelated**.

Hearing Tr. at 59, emphasis added.

We now know, based on Defendants' own admission in Defendants' Reply Memorandum, that the July 30 trauma letter was "*virtually identical* to the July 30 BLA letter in terms of the questions asked,"*Id.*, (emphasis in original), thereby further demonstrating the materiality of the FDA trauma clinical hold to the Hemopure BLA.

For the reasons already presented by Plaintiffs' memoranda and at the Hearing on the Motion to Amend, which Defendants' factual admission discussed herein further underscores, the Second Consolidated Amended Complaint more than adequately pleads that Defendants' statements regarding the Hemopure BLA and the trauma studies during the Class Period were false, deceptive and misleading and this Court should grant Plaintiffs' Motion to Amend Complaint.[3]

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[3] Obviously, the newly discovered fact that the FDA's July 30, 2003 BLA Complete Response Letter and the FDA's July 30, 2003 letter reaffirming the Trauma Clinical Hold were

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Respectfully submitted,

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Certificate of Service

I hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing ("NEF") and paper copies will be sent to those indicated as nonregistered participants on the 13th day of March, 2006.

/s/ Edward F. Haber
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"*virtually identical*" could be added to the proposed Second Consolidated Amended Complaint.